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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/492,361	01/27/2000	Thomas J. Jentsch	2815-127P	9782

2292 7590 10/21/2002

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/21/2002 15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/492,361

Applicant(s)

JENTSCH, THOMAS J.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-19, 21-45, 47 and 49-61 is/are pending in the application.
- 4a) Of the above claim(s) 12-17, 31-45, 47 and 49-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 18-29 and 59-61 is/are rejected.
- 7) ☒ Claim(s) 7-8, 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Formal Matters***

Claim 1 was amended in Paper No. 16, 6/27/2002. Claims 1-8, 10-19, 21-45, 47, 49-61 are pending. Claims 12-17, 31-45, 47, 49-58 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 1-11, 18-19, 21-30, 59-61 are under consideration.

### ***Response to Amendment***

The rejection of claims 1, 3-8, 10-11, 18-19, 21-30, 59 and 61 under 35 U.S.C. 102(b) as being anticipated by Singh et al. (1998) has been withdrawn based on the Declaration of Dr. Bo Skaaning, Paper No. 17, 7/15/2002.

The rejection of claims 1, 3-8, 10-11, 18-19, 21-30, 59 and 61 35 U.S.C. 103(a) as being unpatentable over Singh et al. (1998) in view of WO 9401548 (Sibson et. Al) has been withdrawn based on the Declaration of Dr. Bo Skaaning, Paper No. 17, 7/15/2002.

### ***Claim Rejections - 35 USC § 112***

Claims 1-6, 18-30, 59-61 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide having a sequence as set forth in SEQ ID NO: 1, does not reasonably provide enablement for an isolated polynucleotide wherein the polynucleotide is at least 90% homologous to the nucleotide sequence set forth in SEQ ID NO: 1, or an isolated polynucleotide capable of hybridizing under the conditions set forth in claim 1 to the polynucleotide sequence of SEQ ID NO: 1, for reasons of record set forth in Paper No. 14, 2/22/2002. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is based upon the evidence presented in the Bowie et al. reference showing that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex, and the Mikayama et al. and Voet et al. references which demonstrates that the change of a single amino acid can radically alter protein function, and that because of this unpredictability of the protein art insufficient guidance is provided how to make or use the myriad of variant or mutated polypeptide species encoded by the claimed polynucleotides.

Applicant argues that the specification provides enablement by providing functional assays for the sequence variants encompassed by the claim. However, the functional limitation provided wherein the polynucleotide encodes an amino acid sequence having activity as a KCNQ4 potassium channel subunit is insufficient to allow one of skill in the art to determine whether a sequence variant is encompassed by the claim, because it is unclear which activity of a KCNQ4 potassium channel is required. Addition of a functional limitation where in the polynucleotide encodes an amino acid sequence which is an outwardly rectifying potassium channel would obviate this rejection.

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Claims 1-6, 18-30, 59-61 stand rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in Paper No. 14, 2/22/2002.

The basis for the rejection is that these are genus claims, and that in the specification (page 5, lines 10), Applicants disclose that the mutated polynucleotide may be a polynucleotide of the invention having a nucleotide sequence encoding a potassium channel having an amino acid sequence that has been changed at one or more positions. The specification and claims do not indicate what distinguishing attributes shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted

Applicant argues that the specification provides written description by providing functional assays for the sequence variants encompassed by the claim. However, the functional limitation provided wherein the polynucleotide encodes an amino acid sequence having activity as a KCNQ4 potassium channel subunit is insufficient to describe the claimed genus, because it is unclear which activity of a KCNQ4 potassium channel is required. Addition of a functional limitation where in the polynucleotide encodes an amino acid sequence which is an outwardly rectifying potassium channel would obviate this rejection.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 21 recite the limitation "said variant" in line 2. There is insufficient antecedent basis for this limitation in the claim. The term "variant" does not appear in the claims these are dependent upon.

***Conclusion***

Claims 1-6, 10, 18-30, 59-61 are rejected.

Claims 7-8, 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
October 7, 2002